

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

Claims 1-87 (Canceled).

88. A topotecan monohydrochloride pentahydrate product having an X-ray powder diffraction pattern that is substantially the same as Figure 1.

89. A topotecan monohydrochloride pentahydrate product having an inverse second derivative FT-IR spectrum for the spectral region of  $1800\text{ cm}^{-1}$  -  $1500\text{ cm}^{-1}$  that is substantially the same as Figure 3.

90. The product according to claim 88, wherein the product has a water content range between from about  $\geq 10\%$  w/w% to about  $\leq 17$  w/w%.

91. The product according to claim 88, wherein the product has a water content in a range of about 10.5 wt% to about 16.5 wt%.

92. The monohydrochloride pentahydrate product having an X-ray diffraction pattern that is substantially the same as Figure 1,

wherein the product is prepared by a process comprising the steps of:

[a] forming an aqueous organic solvent mixture containing topotecan monohydrochloride, wherein the organic solvent of the aqueous organic solvent mixture is selected from the group consisting of acetone and tetrahydrofuran, and wherein the ratio of organic solvent to aqueous solvent in the aqueous organic solvent mixture is from about 1.5:1 to about 3:1;

[b] recrystallizing the topotecan monohydrochloride from the aqueous organic solvent mixture to precipitate the topotecan monohydrochloride pentahydrate product; and

[c] collecting, by filtration, the topotecan monohydrochloride pentahydrate product.

93. The product according to claim 92, wherein the aqueous organic solvent mixture comprises an aqueous mineral acid solution.

94. The product according to claim 92, wherein the aqueous mineral acid solution is a 0.05 N aqueous hydrochloric acid solution.

95. The product according to claim 92, wherein the aqueous organic solvent mixture comprises a mixture of acetone and a 0.05 N aqueous hydrochloric acid solution.

96. The product according to claim 92, wherein process step [b] comprises recrystallizing the topotecan monohydrochloride from the aqueous organic solvent mixture which comprises acetone and 0.05 N aqueous hydrochloric acid, wherein the v/v ratio of acetone to aqueous hydrochloric acid is about 2:1.

97. The product according to claim 92, prepared by a process further comprising the steps of:

- first dissolving topotecan monohydrochloride in a heated aqueous organic solvent solution mixture;
- crystallizing or recrystallizing the topotecan monohydrochloride pentahydrate from the heated solution by cooling the solution; and
- filtering the resulting recrystallized topotecan monohydrochloride pentahydrate product and drying.

98. The product according to claim 97, wherein the heated aqueous organic solvent solution mixture is a mixture of acetone and 0.05 N aqueous hydrochloric acid

heated to a temperature of about 58°C and the v/v ratio of acetone to aqueous hydrochloric acid is about 2:1.

99. The product according to claim 97, wherein the heated solution is cooled at a rate of about 0.1°C/min to about 1°C/min.

100. The product according to claim 97, wherein the heated solution is cooled at a rate of about 0.25°C/min.

101. The product according to claim 97, wherein, in the crystallization or recrystallization process, the solution is cooled to a temperature of about room temperature to about 0°C.

102. A topotecan monohydrochloride pentahydrate product having an X-ray diffraction pattern that is substantially the same as Figure 1,

wherein the product is prepared by a process comprising the steps of:

[a] forming an aqueous organic solvent mixture containing topotecan monohydrochloride, wherein the aqueous solvent of the aqueous organic solvent mixture is an aqueous mineral acid solution, the organic solvent of the aqueous organic solvent mixture is selected from the group consisting of acetone and tetrahydrofuran, and wherein the v/v ratio of organic solvent to aqueous solvent is about 8:1;

[b] slurring the topotecan monohydrochloride with the aqueous organic solvent mixture to form the topotecan monohydrochloride pentahydrate product; and

[c] collecting, by filtration, the topotecan monohydrochloride pentahydrate product.

103. The product according to claim 102, wherein the aqueous organic solvent mixture comprises a 0.05 N aqueous hydrochloric acid solution.

104. A pharmaceutical composition which is a hard gelatin capsule encapsulating a dispersion of topotecan monohydrochloride pentahydrate product in a

mixture of glyceryl monostearate and hydrogenated vegetable oil, prepared by dispersing the topotecan monohydrochloride pentahydrate product according to claim 88 in a mixture of glyceryl monostearate and hydrogenated vegetable oil.

105. A pharmaceutical composition which is a hard gelatin capsule encapsulating a dispersion of topotecan monohydrochloride pentahydrate product in a mixture of glyceryl monostearate and hydrogenated vegetable oil, prepared by dispersing the topotecan monohydrochloride pentahydrate product according to claim 92 in a mixture of glyceryl monostearate and hydrogenated vegetable oil.

106. A process for preparing the product according to claim 88 comprising the steps of:

[a] forming an aqueous organic solvent mixture containing topotecan monohydrochloride, wherein the organic solvent of the aqueous organic solvent mixture is selected from the group consisting of acetone and tetrahydrofuran;

[b] recrystallizing the topotecan monohydrochloride from the aqueous organic solvent mixture to precipitate the topotecan monohydrochloride pentahydrate product; and

[c] collecting, by filtration, the topotecan monohydrochloride pentahydrate product.

107. The process according to claim 106, wherein the aqueous organic solvent mixture comprises an aqueous mineral acid solution.

108. The process according to claim 107, wherein the aqueous mineral acid solution is a 0.05 N aqueous hydrochloric acid solution.

109. The process according to claim 106, wherein the aqueous organic solvent mixture comprises a mixture of acetone and a 0.05 N aqueous hydrochloric acid solution.

110. The process according to claim 106, wherein step [b] comprises recrystallizing the topotecan monohydrochloride from the aqueous organic solvent mixture which comprises acetone and 0.05 N aqueous hydrochloric acid, wherein the v/v ratio of acetone to aqueous hydrochloric acid is about 2:1.

111. The process according to claim 106, further comprising:

- first dissolving topotecan monohydrochloride in a heated aqueous organic solvent solution mixture;
- crystallizing or recrystallizing the topotecan monohydrochloride pentahydrate from the heated solution by cooling the solution; and
- filtering the resulting recrystallized topotecan monohydrochloride pentahydrate product and drying.

112. The process according to claim 111, wherein the heated aqueous organic solvent solution mixture is a mixture of acetone and 0.05 N aqueous hydrochloric acid heated to a temperature of about 58°C and the v/v ratio of acetone to aqueous hydrochloric acid is about 2:1.

113. The process according to claim 111, wherein the cooling rate is in the range of about 0.1°C/min to about 1°C/min.

114. The process according to claim 111, wherein, in the crystallization or recrystallization process, the solution is cooled to a temperature of about room temperature to about 0°C.

115. A process for preparing the product according to claim 88 comprising the steps of:

[a] forming an aqueous organic solvent mixture containing topotecan monohydrochloride, wherein the aqueous solvent of the aqueous organic solvent mixture is an aqueous mineral acid solution, the organic solvent of the aqueous organic solvent

mixture is selected from the group consisting of acetone and tetrahydrofuran, and wherein the v/v ratio of organic solvent to aqueous solvent is about 8:1

[b] slurring the topotecan monohydrochloride with the aqueous organic solvent mixture to form the topotecan monohydrochloride pentahydrate product; and

[c] collecting, by filtration, the topotecan monohydrochloride pentahydrate product.

116. The process according to claim 115, wherein the aqueous organic solvent mixture comprises a mixture of acetone and a 0.05 N aqueous hydrochloric acid solution.